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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/704,327	11/01/2000	James M. Lipton	256/019	4938

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EXAMINER

WINSTON, RANDALL O

ART UNIT PAPER NUMBER

1654

DATE MAILED: 07/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/704,327

Applicant(s)
Lipton

Examiner
Randall Winston

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1654

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-32 and 34-40 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-32 and 34-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

Acknowledgment is made of receipt and entry of the claims filed on April 22, 2003.

Claims 21-32 and 34-40 are under examination.

The rejection made under 35 U.S.C. 112, second paragraph, set forth in the previous office action has been overcome by Applicant's amendment.

The rejection made under 35 U.S.C. 103(a) set forth in the previous office action has been overcome by Applicant's amendment.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-32 and 34-40 as amended stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lipton et al. Anti-inflammatory Influence of the Neuroimmunomodulator alpha-MSH, *Immunol. Today* 18, pages 140-145 (1997) as well as the admitted state of the art with respect to (SEQ. ID. NO. 4).

Applicant requested that the *prima facie* obviousness rejections to the pending claims in Paper No. 12 based on Rathjen be removed consistent with the above remarks has been

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acknowledged. Therefore, the 103(a) rejection listed in Paper No. 12 has been overcome by applicant.

Based on applicant's amendment in Paper No. 14, applicant's claim a sunburn treatment kit comprising of a liquid impermeable packaging, a carrier, an absorbent material and an alpha-MSH peptide comprising alpha-MSH or an alpha-MSH derivative.

Lipton et al. (see entire document) as well as the admitted state of the art (see, e.g., page 6 lines 6-7) teach that alpha-MSH is well known for the treatment of inflammation. (Please note, as readily admitted by applicants, alpha-MSH is an ancient 13 amino acid peptide - this 13 amino acid peptide corresponds with SEQ. ID. NO. 4) which is well known for the treatment of sunburn inflammatory. Lipton et al. do not expressly teach alpha-MSH (which corresponds to Seq. ID. NO. 4) contained within a kit that includes liquid impermeable packaging, a carrier and an absorbent material.

However, one of ordinary skill in the art would have been motivated to incorporate the anti-inflammatory alpha-MSH taught by Lipton et al. (and admittedly well known in the art within a conventional anti-inflammatory kit such as instantly claimed - i.e. the adjustment of other conventional working conditions (e.g., incorporating the anti-inflammatory alpha-MSH within liquid impermeable packaging containing a conventional carrier and an absorbent material therein so as easily and efficiently treat skin inflammation such as that caused by sunburn) is deemed merely a matter of judicial selection and routine optimization which is well within the purview of the skilled artisan to create a kit to treat inflammation.

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Accordingly, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is (703) 305-0404. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600

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receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner,
Brenda Brumback whose telephone number is (703) 306-3220.

row

A handwritten signature in black ink, consisting of a stylized 'C' and 'R' intertwined, followed by a horizontal line.

CHRISTOPHER R. TATE
PRIMARY EXAMINER